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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Collagen Ribbon Tissue Matrix.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	December 29, 2011
Contact Person:	Leslie Fitch Regulatory Affairs Specialist (901) 867-4120
(a)(2). Proprietary Name:	Collagen Ribbon Tissue Matrix
Common Name:	Animal-derived, surgical mesh
Classification Name and Reference:	21 CFR 878.3300 – Class II
Device Product Code and Panel Code:	FTM: Surgical Mesh
(a)(3). Predicate Device:	K073219 – WMT Collagen Ribbon

(a)(4). Device Description

The subject Collagen Ribbon Tissue Matrix is a narrow, ribbon-like version of the predicate WMT Collagen Dermal Matrix (rebranded BIOTAPE XM® Tissue Matrix - K073219). The ribbon-like dimensions of the subject device allow for new surgical techniques compared to the predicate without changing the intended use—reinforcement of soft tissue in orthopedic applications. The subject Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner.

(a)(5). Intended Use

The Collagen Ribbon Tissue Matrix is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, peroneal, posterial tibial, and other tendons. The Collagen Ribbon Tissue Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair. Sutures used to repair the tear and suture or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

The indications for Collagen Ribbon are the same as the legally marketed predicate device with the addition of 2 additional specific tendons. The specific tendons were evaluated for safety and effectiveness through a clinical literature review. A summary of the literature review is provided in the Premarket Notification.

(a)(6). Technological Characteristics Comparison

The technological characteristics of the Collagen Ribbon Tissue Matrix are substantially equivalent to technological characteristics of the predicate identified in this 510(k) submission. The subject Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner. The ribbon-like dimensions of the subject device allow for new surgical techniques compared to the predicate without changing the intended use—reinforcement of soft tissue in orthopedic applications.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Due to the similarities of the subject device with the predicate, biocompatibility, animal, histological, and bench testing results from 510(k) K073219 are applicable to this submission. The subject material has passed all biocompatibility testing including: cytotoxicity, maximization test, intracutaneous reactivity, systemic toxicity implantation (2wk & 13 wk), pyrogenicity, subchronic toxicity & chronic toxicity, carcinogenicity, hemolysis, and genotoxicity. The biocompatibility testing that was previously conducted was in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58. Exempt from Good Laboratory Practice were the characterization and stability of the test article, according to 21 CFR, Parts 58.105 and 58.113. Animal results indicated cellular infiltration and revascularization characteristics. Histology results indicated that the Collagen Ribbon is a decellularized, intact collagen matrix.

A Design Failure Modes and Effects Analysis was used to identify appropriate testing to demonstrate specification conformance for Collagen Ribbon material. Mechanical testing presented in K073219 characterized the suitability of this material in orthopedic applications. Functional and in vivo performance testing confirms that the addition of a second Tyvek barrier to packaging does not alter performance of the material. In addition, mechanical and rehydration testing of Collagen Ribbon demonstrate that Collagen Ribbon maintains the same minimum performance characteristics as the predicate device.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The subject Collagen Ribbon is the identical source material to the predicate and is manufactured and sterilized in the same manner. Substantial equivalence is confirmed through tensile and suture retention testing, rehydration testing, and surgical technique validation studies. The data and evidence presented in this Premarket Notification, the subject device maintains the same minimum performance characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 3 2012

Wright Medical Technology, Inc.
% Ms. Leslie Fitch
5677 Airline Road
Arlington, Tennessee 38002

Re: K120019
Trade/Device Name: Collagen Ribbon Tissue Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: December 29, 2011
Received: January 03, 2012

Dear Ms. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

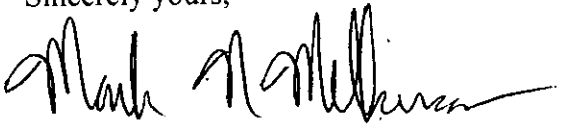
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120019

Device Name: Collagen Ribbon Tissue Matrix

Indications for Use:

The Collagen Ribbon Tissue Matrix is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, peroneal, posterial tibial, and other tendons. The Collagen Ribbon Tissue Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair. Sutures used to repair the tear and suture or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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David Krause for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120019